

## REMARKS

Claims 1 – 25, 27 – 29 and 31 – 38 are pending in the present application. Claims 26 and 30 are canceled without prejudice or disclaimer. By amending any claims herein and/or canceling any claims, Applicants make no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert any of the claims canceled herein or the original claim scope of any claim amended herein, in a continuing application.

Claims 1, 4, 9, 19, 31 – 34, 36 and 37 have been amended, for the sole reason of advancing prosecution. Support for these amendments appears throughout the specification and claims as originally filed. For example, please see the originally filed specification at page 11 lines 5 to 9 and at least figures 1A and 1B. No new matter has been added. In view of the following, further and favorable consideration is respectfully requested.

- I. At page 2 of the Official Action, the Examiner rejected claims 26 and 31 – 32 under 35 USC § 112, second paragraph as being indefinite for being device claims that recite intended use.***

By this Amendment and Response, Applicants have cancelled claim 26, thereby making the rejection thereto moot. The Examiner indicated that claims 31 and 32 were rejected by virtue of their dependence from claim 26. Applicant therefore asserts that the rejection to claims 31 and 32 is also moot. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection under 35 U.S.C. §112, second paragraph.

**II. At page 2 of the Official Action, the Examiner rejected claims 1 – 2, 5, 7, 9 – 10, 12 – 13, 19, 24, 26 and 34 – 35 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,925,446 to Garay et al.**

By this Amendment and Response, Applicants respectfully traverse the rejection since U.S. Patent No. 4,925,446 (hereinafter referred to as “Garay et al.”) does not disclose all of the elements of the presently claimed subject matter. For a reference to anticipate a claim, all of the elements of that claim must be present in the reference. The test for anticipation under 35 U.S.C. § 102 is whether each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference. *Impax Laboratories Aventis v. Pharmaceuticals*, 468 F.3d 1366, 1381 (Fed. Cir. 2006).

Independent claim 1 recites “[a]n implantable medical device for insertion into a body cavity, comprising a balloon having a wall and a lumen and having a torroidal shape defining a hole, and an insert configured to be received and secured in the hole by grooves and ridges on an external surface of the insert which are received in complementary grooves and ridges on an external surface of a wall of the hole.” Independent claims 19 and 34 recite similar features.

Garay discloses a device for drug delivery that includes an inflatable member, an inflation tube and an agent-containing cartridge. Fig. 5 of Garay shows cartridges 13 containing an agent to be released. The cartridges are inserted into a channel 28 of a balloon 27. The cartridges are maintained in the channel 28 by means of perforated caps 29. However, in contrast to the presently claimed subject matter, Garay does not disclose “an insert configured to be received and secured in the hole by grooves and ridges on an external surface of the insert which are received in complementary grooves and ridges on

an external surface of a wall of the hole” as recited in amended independent claim 1 and as similarly recited in amended independent claims 19 and 34.

Thus, as all of the features of the presently claimed subject matter are not disclosed by the cited prior art, the Applicants submit that the cited prior art does not anticipate the presently claimed subject matter. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejections.

***III. At page 3 of the Official Action, the Examiner rejected claims 1 – 29 and 31 – 38 under 35 U.S.C. §102(b) as being clearly anticipated by U.S. Patent No. 6,398,718 to Yachia et al.***

By this Response and Amendment, Applicants respectfully traverse the rejection since U.S. Patent No. 6,398,718 to Yachia et al. (hereinafter referred to as “the ‘718 patent”) does not disclose all of the elements of the presently claimed subject matter. For a reference to anticipate a claim, all of the elements of that claim must be present in the reference. The test for anticipation under 35 U.S.C. §102 is whether each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference. *Impax Laboratories Aventis v. Pharmaceuticals*, 468 F.3d 1366, 1381 (Fed. Cir. 2006).

Independent claim 1 recites “[a]n implantable medical device for insertion into a body cavity, comprising a balloon having a wall and a lumen and having a torroidal shape defining a hole, and an insert configured to be received and secured in the hole by grooves and ridges on an external surface of the insert which are received in complementary grooves and ridges on an external surface of a wall of the hole.” Independent claims 19, 34, 36 and 37 recite similar features.

The '718 patent discloses an "Intravesicular Device." The Examiner alleges that the balloon of this patent has a "hole or chamber and an insert." The Examiner does not specify what element in the device of this patent he identifies with the hole and insert in the present application, but seems to refer to Figs. 9e and f of the patent. This embodiment has a balloon having a channel extending along a length of a diameter in which a magnet 115 is positioned. The magnet is maintained in the channel by means of arms 935 that project from the wall 940 of the balloon, *see The '718 Patent* at col. 9, lines 41 – 45.

However, in contrast to the presently claimed subject matter and assuming *arguendo* that the magnet of the '718 patent could be equated with the insert of the presently claimed subject matter, the '718 patent does not disclose "an insert configured to be received and secured in the hole by grooves and ridges on an external surface of the insert which are received in complementary grooves and ridges on an external surface of a wall of the hole" as recited in amended independent claim 1 and as similarly recited in amended independent claims 19, 34, 36 and 37.

Thus, as all of the features of the presently claimed subject matter are not disclosed by the cited prior art, the Applicants submit that the cited prior art does not anticipate the presently claimed subject matter. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejections.

***IV. At page 3 of the Official Action, the Examiner rejected claims 1, 2, 5, 7, 19 – 20, 24 – 26 and 33 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Publication No. 2002/0151923 to Holzer.***

By this Amendment and Response, Applicants respectfully traverse the rejection since U.S. Patent Application Publication No. 2000/0151923 to Holzer (hereinafter referred

to as "Holzer") does not disclose all of the elements of the presently claimed subject matter.

For a reference to anticipate a claim, all of the elements of that claim must be present in the reference. The test for anticipation under 35 U.S.C. §102 is whether each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference. *Impax Laboratories Aventis v. Pharmaceuticals*, 468 F.3d 1366, 1381 (Fed. Cir. 2006).

Independent claim 1 recites "[a]n implantable medical device for insertion into a body cavity, comprising a balloon having a wall and a lumen and having a torroidal shape defining a hole, and an insert configured to be received and secured in the hole by grooves and ridges on an external surface of the insert which are received in complementary grooves and ridges on an external surface of a wall of the hole." Independent claim 19 recites similar features.

Holzer discloses a device and method for aiding urination. Fig. 2 of Holzer shows a balloon 4 having a channel 55 surrounding a tubular element 2. The tubular element is anchored to the balloon, preferably, by a flexible strip 6 (par 62). Holzer does not mention retaining the tubular element in the channel by a system of grooves and ridges. However, in contrast to the presently claimed subject matter, Holzer does not disclose "an insert configured to be received and secured in the hole by grooves and ridges on an external surface of the insert which are received in complementary grooves and ridges on an external surface of a wall of the hole" as recited in amended independent claim 1 and as similarly recited in amended independent claim 19.

Thus, as all of the features of the presently claimed subject matter are not disclosed by the cited prior art, the Applicants submit that the cited prior art does not anticipate the

presently claimed subject matter. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejections.

## CONCLUSION

Applicants assert that the claims are in condition for immediate allowance and early notice to that effect is earnestly solicited. Should the Examiner deem that any further action by Applicants' undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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